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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/046,667	01/16/2002	Domenica Simms	0942.5220001/RWE/CJW	3021

26111            7590            08/25/2003  
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WASHINGTON, DC 20005

EXAMINER
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PRATS, FRANCISCO CHANDLER

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 08/25/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/046,667	SIMMS, DOMENICA	
	<b>Examiner</b>	<b>Art Unit</b>	
	Francisco C Prats	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on \_\_\_\_.  
 2a) This action is **FINAL**.                    2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-24 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_ is/are allowed.  
 6) Claim(s) 1-8 and 11-24 is/are rejected.  
 7) Claim(s) 9 and 10 is/are objected to.  
 8) Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 11) The proposed drawing correction filed on \_\_\_\_ is: a) approved b) disapproved by the Examiner.  
     If approved, corrected drawings are required in reply to this Office action.  
 12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
 \* See the attached detailed Office action for a list of the certified copies not received.  
 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
 a) The translation of the foreign language provisional application has been received.  
 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)                    4) Interview Summary (PTO-413) Paper No(s). \_\_\_\_ .  
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)                    5) Notice of Informal Patent Application (PTO-152)  
 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_ .                    6) Other: \_\_\_\_\_

**DETAILED ACTION**

Claims 1-24 are presented for examination.

***Information Disclosure Statement***

Note that several of the pending applications cited by applicant in the PTO Form 1449 were lined through as not being considered. The instant application does not have an assignee on file. Thus, it is not clear that the lined-through applications are in fact from the same assignee as the instant case. Moreover, the lined-through applications do not have any inventors in common with the instant application, and have not been published. If the instant application were to issue as a patent, the lined-through applications, if considered, would become public record, despite no clear evidence on the current record that applicant has the authority to publicly disclose those applications. Clarification of this issue is suggested.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2 and 11-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

With respect to claim 2, the recitation "e.g." is the same as the recitation "for example," which renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05(d). Also, the use of parentheses in the claim renders that claim and its dependents indefinite because it is not clear whether the parenthetical material is merely exemplary, or a positive recitation of a claim limitation.

The recitation "at least one of" in claims 11 and 16 renders those claims and their dependents indefinite. Specifically, the preamble of claims 11 and 16 suggests that those claims encompass only one of the process steps set forth therein. However, the claims are drafted in a manner requiring performance of the previous step. See, e.g., claim 11 (". . . separating cellular debris from **said extract**") (emphasis added). It is therefore confusing how only one of the steps can be required, since the language of the body of the claim requires successive steps to be performed. Because the preamble and the

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body of the claim are inconsistent, a holding of indefiniteness is required.

Lastly, note the typographical error in claim 18, reciting the elution of RNA "form said solid matrix." (Emphasis added.) It appears that the word "form" should be the word -- from --.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Babiuk et al (U.S. Pat. 5,585,264).

Babiuk discloses the digestion with of proteins in a buffer containing the following ingredients:

50 mM Trishydrochloride (pH 8.6),  
25 mM EDTA,  
1% Triton X100,  
1% 2-mercaptoethanol,  
0.2% SDS, and  
1.5 U of enzyme.

See column 51, lines 47-50. Note specifically that Triton X100 is a tert-octylphenoxy poly(oxyethylene) ethanol non-ionic detergent. Note further that detergents are known to lyse

microorganisms. Thus, claim 2 is considered to be anticipated because of the presence of the detergents in the composition. Because Babiuk discloses a composition containing the claimed ingredients in the claimed amounts, a holding of anticipation is required.

Claims 1-7, 11-15 and 19-23 are rejected under 35 U.S.C. 102(b) as being anticipated by Chung et al (Molecules and Cells 6(1):108-111 (1996)).

Chung discloses the use of a buffer containing the following ingredients in preparing RNA from oilseeds:

200 mM Tris-HCl (pH 8.5),  
1.5% SDS,  
300 mM LiCl,  
10 mM EDTA (pH 8.0),  
1% sodium deoxycholate,  
1% NP-40 (w/v),  
5 mM thiourea, and  
10 mM DTT.

See page 109, left column, "Extraction Buffer A." Note specifically that NP-40 is a tert-octylphenoxy poly(oxyethylene) ethanol non-ionic detergent. Note further that detergents are known to lyse bacterial cells. Note still further that, in the proper concentrations, salts are known to be used as antibacterial agents. Thus, claim 2 is considered to be anticipated because of the presence of the detergents and

lithium chloride in the buffer composition. A holding of anticipation over the product claims is clearly required.

Chung's process of extracting the RNA from oilseeds includes the steps of pulverization, homogenization, separation of debris using both centrifugation and filtration, organic extraction using chloroform, and alcohol precipitation. See page 109, paragraph spanning left and right hand columns. Thus, a holding of anticipation over the cited process claims is clearly required.

Lastly, claims 22 and 23, directed to kits, are considered to be anticipated by Chung because a kit merely requires that the stated items be assembled together in close proximity. Because Chung necessarily assembled the claimed items together in close proximity, as evidenced by their use in the claimed process, a holding of anticipation is required over the kit claims.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at

the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 16-18 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chung et al (Molecules and Cells 6(1):108-111 (1996)) in view of Gillespie et al (U.S. Pat. 5,155,018).

As discussed above, Chung discloses the use of a buffer containing the ingredients recited in claim 1, in preparing RNA from oilseeds. Chung differs from claims 16-18 and 24 in failing to use an agent which preferentially binds RNA in the purification procedure. However, Gillespie clearly discloses that the use of such preferential binding matrices is advantageous in the preparation of RNA. See, e.g., columns 1 and 2, discussing the shortcomings of previous methods and the simplicity and effectiveness of the disclosed methods. Thus, the artisan of ordinary skill performing Chung's process, recognizing from Gillespie the advantages of a preferential RNA binding matrix, clearly would have been motivated to have included a step of purifying the RNA using Gillespie's preferential binding matrix, so as to afford the advantages disclosed by Gillespie. A holding of obviousness over the cited claims is therefore clearly required.

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No claims are allowed. Claims 9 and 10 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Francisco C Prats whose telephone number is 703-308-3665. The examiner can normally be reached on Monday through Friday, with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G Wityshyn can be reached on 703-308-4743. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

  
Francisco C Prats  
Primary Examiner  
Art Unit 1651

FCP